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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,352

11/02/2006

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

08/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,352	Applicant(s) USHIJIMA ET AL.	
	Examiner Ethan Whisenant, Ph.D.	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

ELECTION / RESTRICTION

1. **Claim(s) 1-27** as originally filed 29 NOV 01 is/are pending in this application.

LACK OF UNITY

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claim(s) 1-19, drawn to a method(s) of assessing a cancerous state of a mammalian derived specimen which comprise measuring the methylation frequency of the Fibrillin2 gene.

Group II, Claim(s) 20-21, drawn to a method of searching for a substance having the ability to promote the expression of the Fibrillin2 gene.

Group III, Claim 22 drawn to an anti-cancer agent having the ability to promote the expression of the Fibrillin2 gene.

Group IV, Claim(s) 23, drawn to anti-cancer agent which comprises a nucleic acid comprising a nucleotide sequence encoding an amino acid sequence of the Fibrillin2 gene.

Group V, Claim(s) 26-27, drawn to a method of inhibiting canceration (i.e. treating/preventing cancer) which comprises administering, to a subject in need thereof, a substance which reduces a methylation frequency of Fibrillin2 gene.

3. Please note that **Claims 24-25** have not been included in the Lack of Unity as they encompass unpatentable subject matter. Please note that “the use of” is not a patentable category under 35 USC 101.

4. **Groups I and II** lack unity :

Groups I - V, as drawn, do not relate to a single general inventive concept because the claims are not linked by the same or corresponding special technical feature. Groups I -V, as drawn, are not linked by the same or corresponding special technical feature, which by definition, is the limitation or set of limitations which distinguish over the prior art. Without a special technical feature linking the claims, the claims lack unity. If however, it is asserted that the special technical feature is the Fibrillin2 gene the one limitation(s) common to all of the groups, then the examiner notes that the Fibrillin2 gene was known, see Zhang et al. [The Journal of Cell Biology 124 : 855-863(1994)] it does not distinguish over the prior art., as such the claims lack unity.

5. Because these inventions lack unity for the reasons given above, restriction for examination purposes as indicated is proper.

6. The examiner, on 10 AUG 08, attempted, but was unable to reach the applicant regarding an oral election to the above restriction requirement. The applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634